



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. FDA-2022-N-1635]

RIN 0910-AI69

Color Additive Certification; Increase in Fees for Certification Services

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend the color additive regulation to increase the fee for certification services. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act). The fees are intended to recover the full costs of operation of FDA's color certification program.

DATES: Either electronic or written comments on the proposed rule must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for

submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-1635 for "Color Additive Certification; Increase in Fees for Certification Services." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Bryan Bowes, Office of Cosmetics and Colors (HFS-105), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1122; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

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I. Executive Summary

A. Purpose of the Proposed Rule

The proposed rule, if finalized, would amend the color additive regulation to increase the fee for certification services. The change in fees would allow FDA to continue to maintain an adequate color certification program as required by the FD&C Act. The fees are intended to

recover the full costs of operation of FDA's color certification program.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule, if finalized, would amend the color additive regulation to increase the fees for certification services. The fees for straight colors including lakes would be \$0.45 per pound (\$0.10 per pound increase) with a minimum fee of \$288. There would be similar increases in fees for repacks of certified color additives and color additive mixtures.

C. Legal Authority

We are issuing this proposed rule consistent with our statutory which requires that fees necessary to provide, maintain, and equip an adequate color additive certification program be specified in our regulations. FDA also derives authority to issue this proposed rule from the FD&C Act, which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

The proposed rule, if finalized, would amend existing color additive regulations by increasing fees for certification services. The costs of this proposed rule include the cost to read and understand the rule. As the increase in fees is not associated with any change in our certification program, no economic benefits are expected to result from the proposed rule. Similarly, the impact of the increase in certification fees on color additive manufacturers is considered a transfer, rather than an economic cost. Accordingly, we do not estimate economic benefits associated with this proposed rule, and the impact of the increase in color certification fees is estimated as an ongoing transfer from manufacturers of color additives to the Federal Government. The economic burdens of this proposed rule, if finalized, would accrue to color additive manufacturers. We estimate a one-time cost to read and understand the rule for all color additive manufacturers. The present value of this cost is approximately \$1,407 at a 3 percent rate of discount, and \$1,354 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately \$165 at a 3 percent discount rate and \$193 at a 7 percent discount

rate.

II. Background

A. Introduction

Certification of color additives by a self-supporting process has been required since the enactment of the FD&C Act. In accordance with section 721(a)(1)(B) of the FD&C Act, certain color additives must be certified for use by FDA in food, drugs, cosmetics, and medical devices. FDA analyzes samples from each batch of color additive received from a manufacturer and verifies that it meets composition and purity specifications. Certification is performed before the additives are permitted to be used in products. Manufacturers pay fees, based on the weight of each batch for certification. These fees support FDA's color certification program.

In the *Federal Register* of March 29, 2005 (70 FR 15755), we issued an interim final rule (IFR) amending the color additive regulations by increasing the fees for certification services due to a general increase in the cost associated with operating the certification program. The IFR increased the fees per pound. The fee for straight colors including lakes increased from \$0.30 to \$0.35 per pound (a \$0.05 per pound increase) with a minimum fee increase from \$192 to \$224. The fee for repacks of certified color additives and color additive mixtures increased from \$30 to \$35 for 100 pounds or less, from \$30 to \$35 plus \$0.06¹ for each pound over 100 pounds up to 1,000 pounds, and from \$84 to \$89 plus \$0.02 per pound over 1,000 pounds.

B. Need for the Regulation

The current fee schedule specified in part 80 (21 CFR part 80) became effective in 2005 and was amended in 2006. Since 2005, the costs of the certification program have significantly increased because of general operating expenses, including the purchase and maintenance of critical equipment, rent and facility charges, and escalating staff payroll. Therefore, we propose to increase the fees for certifying color additives to reflect increasing operating costs for the

¹ We had originally specified "\$0.05" for each pound over 100 pounds up to 1,000 pounds. Subsequently, in the *Federal Register* of December 7, 2006 (71 FR 70873), we amended the IFR to correct this typographical error.

certification program. The fee schedule for color additive certification, as provided for in our regulations, is designed to cover all the costs involved in certifying batches of color additives. This includes the cost of specific tests required by the regulations and the general costs associated with the certification program, such as costs of accounting, reviewing data, issuing certificates, conducting research, inspecting establishments, and purchasing and maintaining equipment. The current fee schedule is insufficient to provide, equip, and maintain an adequate certification program. Consistent with section 721(e) of the FD&C Act, the proposed increase is necessary to cover increasing operating costs and maintain an adequate color certification program.

III. Description of the Proposed Rule

The proposed rule, if finalized, would revise § 80.10 (21 CFR 80.10), “Fees for certification services,” to:

- increase the fee for certification services from \$0.35 to \$0.45 per pound for straight colors including lakes, and change the minimum fee from \$224 to \$288 (proposed § 80.10(a));
- increase the fees for repacks of certified color additives and color additive mixtures from \$35 for 100 pounds or less to \$45 (proposed § 80.10(b)(1));
- increase the fees for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds, from \$35 plus \$0.06 for each pound over 100 pounds to \$45 plus \$0.08 for each pound over 100 pounds (proposed § 80.10(b)(2)); and
- increase the fees for repacks of certified color additives and color additive mixtures over 1,000 pounds from \$89 plus \$0.02 for each pound over 1,000 pounds to \$114 plus \$0.03 for each pound over 1,000 pounds (proposed § 80.10(b)(3)).

Increasing the fees will ensure the viability of the certification program and offset the increased costs of maintaining this program.

IV. Proposed Effective Date

We propose that any final rule resulting from this rulemaking be effective 30 days after the final rule's date of publication in the *Federal Register*. We believe that this effective date is appropriate because it will provide industry sufficient time to prepare for and adjust to the change in fees.

V. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the increase in fees for color certification services would not significantly increase costs to manufacturers, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets

or exceeds this amount.

B. Summary of Costs and Benefits

This proposed rule, if finalized, would amend existing color additive regulations by increasing fees for certification services. The fee schedule for color additive certification, as provided for in this proposed regulation, is designed to cover all the costs of operation of FDA's color certification program. This includes both the cost of specific tests required by the regulations and the general costs associated with the certification program, such as the costs of accounting, reviewing data, issuing certificates, conducting research, inspecting establishments, and purchasing and maintaining equipment. The fee for certification services of straight colors including lakes would increase from \$0.35 per pound to \$0.45 per pound, with the minimum fee increasing from \$224 to \$288. The fees for repacks of certified color additives and color additive mixtures would increase from \$35 for 100 pounds or less to \$45. The fee for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds would increase from \$35 plus \$0.06 for each pound over 100 pounds to \$45 plus \$0.08 for each pound over 100 pounds. The fee for repacks of certified color additives and color additive mixtures over 1,000 pounds would increase from \$89 plus \$0.02 for each pound over 1,000 pounds to \$114 plus \$0.03 for each pound over 1,000 pounds.

The economic burdens of this proposed rule, if finalized, would accrue to color additive manufacturers. We estimate a one-time cost to read and understand the rule for all color additive manufacturers. The present value of this cost is approximately \$1,407 at a 3 percent rate of discount, and \$1,354 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately \$165 at a 3 percent discount rate and \$193 at a 7 percent discount rate. Because the value of these impacts is small relative to manufacturer revenues, we assume that the supply of color additives would not be affected by this proposed rule. Consequently, we estimate no other impacts associated with this proposed rule.

As noted in the preamble, the fees are intended to recover the full costs of operation of

FDA's color certification program. Since 2005, the costs of the certification program significantly increased as a result of escalating staff payroll, rent and facility charges, as well as general operational expenses, including purchasing and maintaining equipment. As the increase in fees is not associated with any change in our certification program, no economic benefits are expected to result from the proposed rule, if finalized. Similarly, the impact of the increase in certification fees on color additive manufacturers is considered a transfer, rather than an economic cost. Accordingly, we do not estimate economic benefits associated with this proposed rule, and the impact of the increase in color certification fees is estimated as an ongoing transfer from manufacturers of color additives to the Federal Government. Our estimates are summarized in table 1.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of Proposed Rule (Millions of 2020 Dollars Over 10-Year Time Horizon)

[illegible]

C. Summary of Regulatory Flexibility Analysis

We have examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities. Consequently, this analysis, together with other relevant sections of this document and the preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded, under 21 CFR 25.30(h), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the

various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. FDA invites comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

X. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA, “Color Additive Certification; Increase in Fees for Certification Services” Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. Available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects in 21 CFR Part 80

Color additives, Cosmetics, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 80 be amended as follows:

PART 80--COLOR ADDITIVE CERTIFICATION

1. The authority citation for part 80 continues to read as follows:

Authority: 21 U.S.C. 371, 379e.

2. In § 80.10, revise paragraphs (a) and (b) to read as follows:

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (2) shall be \$0.45 per pound of the batch covered by such requests, but no such fee shall be less than \$288.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (4) shall be:

(1) 100 pounds or less - \$45.

(2) Over 100 pounds but not over 1,000 pounds - \$45 plus \$0.08 for each pound over 100 pounds.

(3) Over 1,000 pounds - \$114 plus \$0.03 for each pound over 1,000 pounds.

* * * * *

Dated: October 21, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

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